

Protocol for Adult Human Cardiac Transplantation

I. Preoperative Period

A. Selection of a recipient

1. The recipient should be a patient with terminal heart disease for whom no other treatment is available and for whom life expectancy is limited to days or weeks.

The following will be done:

- a. Full cardiac workup, including cardiac catheterization and angiocardiographic studies.
- b. Elimination of any cardiac lesion treatable by currently acceptable methods.
- c. Elimination of any other general medical condition which would sharply limit the life span of the patient.

B. Selection of a donor

1. The donor shall be an individual whose death is imminent from irreversible noncardiac disease.
 - a. Evaluation of potential donor
 - (1) Medical review - all medical data will be evaluated to establish suitability of the donor, with particular emphasis to insure exclusion of malignancy and occult infection.
 - (2) Cardiac evaluation - all clinical and, when indicated, laboratory studies (cardiac catheterization and angiocardiology) will be performed to establish the suitability of the potential donor heart.
 - (3) Immunologic compatibility - immunologic acceptability will be established if the potential donor could serve as a blood donor for the recipient. Complete red cell antigen typing and histocompatibility studies will be performed to collect data for correlation with potential rejection phenomena.

- (4) Cause of death - a diagnosis of an irreversible cause of imminent death (irreversible brain damage incompatible with life) will be established. The possibility of poisoning must be ruled out.
2. Clinical death of the donor in the presence of an established diagnosis of irreversible brain damage incompatible with life is defined by:
 - a. Fixed, dilated pupils; and no reflexes, spontaneous respiration, or muscle activity.
 - b. Flat isoelectric EEG, no clinical or EEG response to noise or pinch - repeated after 24 hours.

C. Procedures

1. The Principal Investigator will personally establish that the recipient has been selected in the manner specified above, and, in consultation with a neurologist or neurosurgeon, that the criteria for death of the donor have been met.
2. The Principal Investigator, in consultation of the team, will make the final decision as to the suitability of any potential donor and recipient presented to the team for transplantation.
3. The Principal Investigator will personally ascertain that informed, signed consent (attached) has been obtained for the donor, and that informed, signed consent (attached) has been obtained for the recipient.

II. Operative Period

A. The Procedure

Upon clinical death of the donor, as defined above, the donor heart will be excised and perfused. During the perfusion, the donor heart will be evaluated on the basis of visual observation, electrocardiograms, and arterial gas determinations. If the heart is judged to be suitable, the recipient will be placed on cardiopulmonary bypass, and the donor heart will be implanted following established procedure.

III. Postoperative Period

A. Isolation and Monitoring

To insure strict asepsis, the patient will remain in an operating room during the first portion of the postoperative period. During this time, the same monitoring of the patient's condition as employed during the surgical procedure will be continued, and arterial gas and other determinations will be made periodically. A clinical laboratory and a cardiopulmonary technician will be available.

When the patient's condition permits, he will be transferred to the heart study area which has been thoroughly cleaned and furnished with sterilized mattress and bed linen. Every effort will be made to maintain surgical cleanliness in this area.

B. Immunology

Studies to detect onset of graft rejection will be done daily. The principle studies to be performed are clinical cardiac functional evaluation, EKG, leukocyte counts, temperature.

Immediate immunosuppressive measures will consist of administration of ALS and Imuran.

C. Assignment of Team Personnel

To be made by Principal Investigator. Only previously designated personnel observing standard aseptic precautions are to approach the patient.